N.K.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/899,147	07/06/2001	Robert Burgermeister	CRD-949	2811

27777 7590 03/26/2003

AUDLEY A. CIAMPORCERO JR.
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER
BAXTER, JESSICA R

ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 03/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/899,147	Applicant(s) BURGERMEISTER ET AL.	
	Examiner Jessica R Baxter	Art Unit 3731	

-- Th MAILING DATE of this communication appears on the cover sh t with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 January 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *10* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 4, and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,697,971 to Fischell et al.

Regarding claim 1, Fischell discloses a stent comprising a multiplicity of circumferential sets of strut members, each being longitudinally separated from each other (see FIG. 7 and Column 4 lines 25-30), each set of strut members being connected to adjacent sets of strut members by longitudinal connecting links (see FIG.7 undulating links) and each set of strut members forming a closed, ring-like cylindrical portion of the stent, each set of strut members consisting of a multiplicity of connected curved sections and diagonal sections (see FIG. 7 U shaped portions), each curved section having two ends and a center there between, at least one set of strut members having at least half of the curved sections within the set of strut members having a tapered shape wherein the width at the center of a curved section with a tapered shape is greater than the width at the ends of a curved section with tapered shape such that the curved section with tapers outwardly from its center (see FIG. 7 U shaped portions).

Regarding claim 4, Fischell discloses that the stent further comprises a multiplicity of sets of flexible links with each set of flexible links connecting two of the multiplicity of sets of strut members, each set of flexible links consisting of a multiplicity of individual flexible links, each individual flexible link being a single undulating structure that extends generally in the longitudinal

direction that is parallel to the stent's longitudinal axis and each individual flexible link having two ends, each one of the two ends being fixedly attached to one curved section of the multiplicity of sets of strut elements at an attachment point situated between the center and the end of that curved section.

Regarding claim 25, Fischell discloses a stent comprising a multiplicity of circumferential sets of strut members, each set of strut members being longitudinally separated each from the other, at least one set of strut members having a tapered shape wherein the width at the center of a strut portion with a tapered shape is greater than the width at the ends of a strut portion with a tapered shape (see FIG. 7 diagonal and curved portions of U-shaped members).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1, 2, 3, 5, and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,273,911 to Cox et al. in view of U.S. Patent No. 5,922,020 to Klein et al.

Regarding claims 1 and 6, Cox discloses a stent comprising a multiplicity of circumferential sets of strut members, each being longitudinally separated from each other, each set of strut members being connected to adjacent sets of strut members by longitudinal connecting links and each set of strut members forming a closed, ring-like cylindrical portion of the stent, each set of strut members consisting of a multiplicity of connected curved sections and diagonal sections, each curved section having two ends and a center there between (see FIG. 7). Cox does not disclose at

least one set of strut members having at least half of the curved sections within the set of strut members having a tapered shape wherein the width at the center of a curved section with a tapered shape is greater than the width at the ends of a curved section with tapered shape. Klein teaches that tapered shapes are used in the curved sections of at least one of the sets of strut members in order to allow some curved sections to open before the non-tapered curved sections. The distribution of the tapered curved sections allows the stent to open in a generally uniform manner (see Column 3 lines 8-23). Klein also teaches that the tapered regions are provided in some of the curved sections of the sets of strut members so that that the initial expansion of the stent will occur in the tapered region first (see Column 4 lines 9-14). Klein also teaches that the strength of the tapered curved sections of the sets of strut members is controlled by the relative cross-sectional dimension of the different tapered regions. Klein teaches that even slight differences in cross-sectional size affect the performance of the stent (see Column 4 lines 28-65). Klein also teaches that the stress concentration occurs in the apex of the curved sections of the strut members and causes the curved section to yield and thus a tapered region is provided to move the concentration of stress to the sides of the curved sections (see FIGS. 15B and 18B, Column 9 lines 51-67, and Column 10 lines 24-29). It would have been obvious to one having ordinary skill in the art at the time the invention was made to add the tapered curved sections of Klein's stent to each of the curved sections of the stent of Cox in order to allow the stent of Cox to expand with a uniform deployment and to change the location of the concentration of the bending stresses from the apex of the curved section to the sides of the curved section to prevent the apex of the curved section from yielding.

Regarding claim 2, Cox discloses that the stent further comprises that the curved sections of one or more of the sets of strut members have inside and outside surfaces in the shape of circular

arcs each circular arc having a center of curvature with the centers of curvature of the two arcs being longitudinally displaced one from the other (see FIG. 8 portion 66).

Regarding claim 3, Cox, as modified, discloses the claimed invention except for the size of the width of the curved section. It would have been an obvious matter of design choice to change the size of the width of the curved section to be at least .0001 inches greater than the width at the ends of the curved sections, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art.

Regarding claim 5, Cox as modified by Klein discloses that one or more of the curved sections of the sets of the strut members have a tapered shape with a greater width at the center of at least one diagonal section (see Klein FIG. 18B region 130).

5. Claims 7-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al. '971 in view of U.S. Patent No. 5,807,404 to Richter.

Regarding claim 7, Fischell discloses the claimed invention except for the end sets of strut members having shorter strut members than the central sets of strut members. Richter teaches that the strength of the stent at the end is increased by reducing the length of some sections at the stent end (see Column 2 lines 14-17). Richter also teaches that decreasing the length of the end sections of strut members would also minimize flare. It would have been obvious to one having ordinary skill in the art at the time the invention was made to shorten the length of the end sets of strut members of Fischell's stent in order to increase the strength of the stent and minimize flare.

Regarding claim 8, Fischell discloses that all curved sections of every central set of strut members have a tapered shape (see FIG. 7).

Regarding claim 9, Fischell discloses the claimed invention except for the strut width at the center of the curved sections of the end sets of strut members is less than the strut width at the center of the central sets of strut members. Richter teaches that the end sections of strut members need to be more flexible in order to allow the stent to accommodate the vessel in which in which it was implanted. Richter teaches that in order to increase the flexibility of the end sections, the width of end sections of strut members must be decreased relative to the width of central section of strut members (see Column 1 lines 43-66). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the stent of Fischell to include a decreased width in the curved sections of the end sets of strut members relative to the central sections of the strut members in order to provide more flexibility in the ends of the stent in order to allow the stent to accommodate the curvature of a vessel in which it is introduced.

Regarding claim 10, Fischell discloses that the diagonal sections of the central sets of strut members has a tapered shape wherein the width of the at least one diagonal section is different at the center of the diagonal section as compared to the width at either endof that diagonal section (see FIG. 7 diagonal sections of the U members).

Regarding claim 11, Fischell, as modified, discloses the claimed invention except for the width of the diagonal section is less at the center of that diagonal section as compared to the width at either end of that section. Richter teaches that decreasing the width of strut members relative to other strut members increases the flexibility of the stent (see Column 1 lines 43-50). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the stent of Fischell to decrease the width of the diagonal sections of sets of strut members in order to increase the flexibility of the stent.

Regarding claim 12, Fischell discloses that the width of the diagonal section is greater at the center of that diagonal section as compared to the width at either end of that section (see FIG. 7 diagonal sections of the U shaped members).

Regarding claims 13 and 14, Fischell discloses that the diagonal sections of the central and end sets of strut members have a tapered shape (see FIG.7).

6. Claims 15, 16, 17 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al.'971 in view of U.S. Patent No. 5,609,629 to Fearnot et al. Fischell discloses the claimed invention except for the coating of the stent with a plastic material containing parylene and a drug of heparin. Fearnot teaches that parylene is well known for use in the biomedical field (see Column 4 lines 5-12). Fearnot also teaches that bioactive layers can be attached to the porous layer of parylene in order to ensure a controlled release of the bioactive substance (see Column 4 lines 23-39). Fearnot also teaches that heparin may be provided on the stent since it is an antiplatelet or antithrombotic agent (see Column 3 lines 30-49). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a coating of parylene and heparin on the stent of Fischell in order to provide a controlled release of a drug and to provide a drug with antiplatelet or antithrombotic properties.

7. Claims 15, 17, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al. '971 in view of Fearnot et al. '629, further in view of U.S. Patent No. 6,273,913 to Wright et al. Fischell discloses the claimed invention except for the coating of the stent with a polymer containing rapamycin. Wright teaches that rapamycin is capable of inhibiting an inflammatory response caused by stent implantation (see Column 5 lines 36-46). Wright also teaches that a polymer is provided to hold the drug to the stent (see Column 6 lines 1-2). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the stent of Fischell with a

polymer coating in order to hold a drug on the body of the stent and to provide the stent of Fischell with the drug of rapamycin in order to inhibit the inflammatory response that s caused by the implantation of the stent itself.

8. Claims 15, 17, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al.'971 in view of Fearnot et al. '629, further in view of U.S. Patent No. 6,231,600 to Zhong. Fischell discloses the claimed invention except for the coating of the stent with a plastic material that contains the drug Taxol or heparin. Zhong teaches that Taxol or heparin is provided in a polymeric coating in order to release the drugs over a period of time. Zhong teaches that taxol and heparin render the stent non-thrombogenic to prevent the occurrence of restenosis (see Column 2 lines 24-42). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the stent of Fischell with the polymeric coating that contains heparin or taxol in order to make the stent of Fischell non-thrombogenic in order to prevent restenosis.

9. Claims 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al. '971 in view of Fearnot et al. '629 as applied to claims 15, 16, and 17, further in view of U.S. Patent No. 6,368,658 to Schwarz et al. Fischell, as modified, discloses the claimed invention except for the use of phosphorylcholine. Schwarz teaches that phosphorylcholine is a well-known material that can be applied to stents for drug delivery (see Column 6 lines 32-57 and Column 15 lines 41-53). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the stent of Fischell with phosphorylcholine since it is well known in the art to use phosphorylcholine in drug delivery stents.

10. Claims 15 and 22 are are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al. '971 in vie w of U.S. Patent No. 5,725,572 to Lam et al. Fischell discloses the claimed invention except for the polymer coating that contains a radiopaque material. Lam teaches that

providing the stent with a radiopaque marker in the coating allows the stent to be located using fluoroscopy without obscuring the lesion that is to be repaired and without impeding the deformation of the expandable stent (see Abstract and Column 7 lines 14-27). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the stent of Fischell with a polymeric coating containing a radiopaque material in order to locate the position of the stent without obscuring the lesion or impeding the deformation of the expandable stent.

11. Claims 15, 22, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al. '971 in vie w of U.S. Patent No. 6,066,169 to McGuinness. Fischell discloses the claimed invention except for the polymer coating containing tungsten. McGuinness teaches that polymers and tungsten are well known materials to be used in stents (see Column 6 lines 46-52). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the stent of Fischell with a coating containing tungsten and a polymer since these are well known materials employed in stents.

12. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al. '971 in view of Lam et al. '572 as applied to claim15 and 22 above, and further in view of U.S. Patent No. 5,634,946 to Slepian. Fischell, as modified discloses the claimed invention except for the thickness of the coating on the stent. Slepian discloses that the coating of a stent can be customized for an individual clinical situation (see Column 6 lines 45-50). Slepian discloses that varying thicknesses of the coating can be achieved to achieve a required geometry to completely occlude a vessel or deliver therapeutic agents to a specific location (see Column 8 line 66- Column 9 line 8). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify

the coating of the modified stent of Fischell in order to achieve a geometry for a specific clinical application of the stent including the occlusion of a lumen or the delivery of a therapeutic agent.

Response to Arguments

13. Applicant's arguments filed January 10, 2003 have been fully considered but they are not persuasive.

14. Applicant argues that Fischell '971 tapers the curved sections in a different fashion than the claimed invention. However applicant claims that the width of a center of a curved section with a tapered shape is greater than the width at the ends of a curved section with tapered shape such that the curved section tapers outwardly from its center. This is clearly met by Fischell in Figure 7. The width of the curved section is definitely greater than the width of the end portions of the curved section. The curved section tapers outwardly from its center.

Conclusion

15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica R Baxter whose telephone number is 703-305-4069. The examiner can normally be reached on M-F 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Jessica R Baxter
Examiner
Art Unit 3731

jrb
March 10, 2003

DAVID O. REIP
PRIMARY EXAMINER